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(54) Title: CERVICAL VIDEOSCOPIC WITH DETACHABLE CAMERA UNIT		
(57) Abstract		
<p>Aideoscope, particularly adapted to examine the cervix, vagina or colon for cancerous lesions or other abnormalities, comprises a video camera unit (32) adjustable along a guide (34) attached to the fixed blade (10) of a speculum (10, 14). By using the videoscope in combination with a monochromator (54), the physician can step through various wavelengths of the light spectrum to test for fluorescence of abnormal cells. Channels (94, 98, 70) are for providing gas under pressure, for inserting forceps (100) and for providing suction to remove smoke created by the destruction of the cells by a laser beam. The video camera unit (32) can be inserted into a sterile sheath (88), and then attached to the speculum for insertion into the body passage for further examination. The video camera unit (32) can be removed from the sheath (88), resterilized or desinfected and reattached to a sterile speculum for use with another patient.</p>		

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CERVICAL VIDEOSCOPE WITH DETACHABLE CAMERA UNITTechnical Field

This invention relates to a cervical videoscope and particularly to one with a removable camera unit which
05 allows inspection of the cervix and other body passageways under specific selected wavelength of light and provides for subsequent treatment of any lesions found. The camera unit includes a camera, optics and light delivery system, which may also be referred to as
10 an electronic video endoscope.

This application is a continuation-in-part of co-pending U.S. Serial No. 456,469, filed December 22, 1989, which is a division of U.S. Serial No. 291,238, filed December 28, 1988, now U.S. Patent No. 4,905,670.

15 Background Art

Examination of the cervix for cancer and viral infections are done now with a device called a colposcope. This device is a binocular microscope which is placed near the patient. It supplies a bright light,
20 (white light and green light) and the operator looks through the eyepieces of the colposcope much like looking through field glasses. This is done with a vaginal speculum in place. Some of the devices have camera attachments for still picture photography. The
25 physician looks at the tissue looking for whitened areas after treatment with 3-5% acetic acid. The acetic acid

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whitens tissue which is low in mucous, such as cancer cells. The physician also looks for clusters of blood vessels which may indicate new growth such as cancer.

05 The effectiveness of this colposcopy procedure is only 85%, and this is with a very experienced physician doing the procedure. Also, the colposcope is difficult to use because of its size and weight.

Over the years various vaginal speculae have been developed. Among these are the following:

10 Casaneda U.S. Patent No. 4,210,133 discloses a vaginal speculum having a microscope mounted thereon which has a light source for illumination and is longitudinally adjustable for focusing.

15 VanDerBel U.S. Patent No. 4,597,383 discloses a vaginal speculum having optical fiber illumination means attached thereto.

Burgin U.S. Patent No. 4,638,792 has an adjustable speculum with an incorporated light system.

20 Walsh U.S. Patent No. 4,619,248 discloses a light attachment for a speculum.

Wider et al. U.S. Patent No. 4,562,832 illustrates in Figure 6 a fiberoptic light pipe installed in the lower jaw of the vaginal speculum.

25 Burgin U.S. Patent No. 4,502,468 has an adjustable speculum with an incorporated lighting system.

Whitman U.S. Patent No. 3,789,835 discloses an illuminating attachment for vaginal speculum.

30 Stafl U.S. Patent No. 4,300,570 has a diagnostic method of projecting the image of a cervix photograph onto a screen. However, the camera is not mounted to the speculum.

Hasson U.S. Patent No. 3,789,829 discloses a radium

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applicator mounted to a vaginal speculum.

Walden et al. U.S. Patent No. 3,037,505 discloses a speculum with a spray tube carried by a jaw of the speculum.

05 Tanikawa et al. U.S. Patent No. 4,461,558 discloses an endoscopic photographing apparatus applicable to all types of endoscopes and uses thereof.

10 Toyota et al. U.S. Patent No. 4,697,210 discloses an endoscope for observing the interior of a cavity in a human body with the image displayed on a TV screen.

15 The last two patents are representative of many observation techniques available for use with endoscopes.

None of these devices have served to increase the
15 detection rate of cancer and the early treatment thereof.

Disclosure of the Invention

A cervical videoscope apparatus is provided which includes a vaginal speculum having a first fixed blade,
20 a second blade mounted for pivotal movement toward and away from the fixed blade and spring means normally urging the second blade toward the fixed blade. The improvement includes a video camera, optics and light bundle, collectively referred to as an electronic video endoscope or video camera unit. The video camera unit is removably mounted on one of the blades for viewing the cervix, means providing light to the cervix, means for focusing the camera on a selected site on the cervix and means for providing a signal from the camera to a
25 30 video screen for viewing the cervix and identifying lesions thereon. The focusing means may include a track

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mounted longitudinally along one of the blades and means for adjusting the video camera unit along the track for focusing. The light providing means can include a light carrier on the track for providing light to the cervix.

05 In addition, means is provided for selecting light for illumination of the cervix at any one of a range of light frequencies. This can be broad frequency light, monochromatic light or laser light for illumination. A particularly useful light frequency has been found to be
10 from 200 nm through 1100 nm. A suitable means for stepping sequentially through the frequencies is a monochromator. The monochromator converts light from a light source to a single frequency at an output in the form of a rectangular slit. A light carrier is provided.
15 which includes a bundle of optical fibers having a first end in a form of a rectangular collar for receiving the output from the monochromator and a circular collar at the other end for directing a round column of light onto the cervix.

20 A laser carrier can be provided on the track for directing a laser beam or laser fiber to vaporize lesions on the cervix. Also, a suction tube can be provided on the track to remove smoke created when the lesions are vaporized with the laser.

25 The invention also provides a method for locating and surgically removing lesions. This method comprises the steps of selectively illuminating the cervix with a light of different frequencies, observing the cervix as it is illuminated with each light frequency, locating
30 lesions by their fluorescence or reflectance under one of the selected light frequencies and removing the lesions which have been located. The lesions may be removed by

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using a laser to vaporize them and the activation of the laser can be terminated in response to termination of any fluorescence at the lesion site.

The video camera unit is removably attached to one
05 blade of the speculum, as by a flexible strap having a first end fixedly attached to the first side of the track and extending around the video camera unit and having a second end with means for releasably attaching it to the second side of the track. This releasable
10 means may include a pin on the second side of the track, an aperture in the second end of the strap having a diameter just slightly larger than the diameter of the pin so as to be received thereover and a removable fastening means attached to the end of the pin to hold
15 the second end in place.

After removal from the speculum, the video camera unit can be inserted in an outer, cylindrical, heat sterilizable sheath having a window sealed to the distal end thereof and an accordian-folded, heat sterilizable,
20 cylindrical sleeve mounted adjacent to the proximate end of the sheath and extendable along the electronic cable and optical bundle of the video camera unit for a substantial distance for maintaining sterility of the video camera unit within an operating room. Also, means
25 can be provided for releasably locking the video camera unit within the sheath in a predetermined orientation. This releasable locking means may be in the form of a bayonet slot and pin arrangement. The sheath may have a passageway or channel within it for supplying an
30 insufflation gas to distend the area being examined, along with valve means for controlling the flow of gas to the channel. A second channel can also be provided

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with a steerable device or other means for carrying out a procedure on a lesion located at the site.

Afterwards, the video camera unit can be removed from the sheath, resterilized or disinfected and
05 reattached to a sterile speculum for examination of the next patient. The sheath can be thrown away or resterilized for reuse with another patient.

Additional advantages of this invention will become apparent from the description which follows, taken in
10 conjunction with the accompanying drawings.

Brief Description of the Drawings

Figure 1 is a side elevation of a cervical videoscope constructed in accordance with this invention and positioned for use;

15 Figure 2 is an enlarged rear elevation of the cervical videoscope of Figure 1;

Figure 3 is a longitudinal section, taken along line 3-3 of Figure 2; showing further details of the video camera and associated laser tube and suction tube;

20 Figure 4 is a longitudinal section, taken along line 4-4 of Figure 2, showing details of the track mounting for the video camera unit;

Figure 5 is an enlarged cross-section, taken along line 5-5 of Figure 4, showing further details of the video camera unit and track mechanism;

25 Figure 6A is a diagrammatical view of video camera unit used in conjunction with a monochromator;

Figure 6 shows details of the optical bundle connector of Figure 6A for converting a rectangular light slit into a circular beam;

30 Figure 7 is a diagrammatical view showing the video

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camera unit used with a band pass filter to provide monochromatic light;

Figure 8 is a diagrammatical view showing the video camera unit used directly with a light source;

05 Figure 9 is a fragmentary side elevation of a video camera unit and light source attached to the speculum by a releasable strap;

10 Figure 10 is an enlarged vertical section, taken along line 10-10 of Figure 9, showing further details of the removable strap;

Figure 11 is a perspective view of the video camera unit and the sheath into which it is to be inserted;

Figure 12 is a fragmentary perspective view showing the video camera unit inserted within the sheath;

15 Figure 13 is an enlarged, end view of the distal end of the sheath of Figure 12; and

20 Figure 14 is an enlarged vertical section, taken along line 14-14 of Figure 12, showing the interconnection between the video camera unit and the sheath.

Best Mode For Carrying Out the Invention

In accordance with this invention a cervical videoscope V is attached to a speculum S, as shown in Figure 1. In use, the speculum is inserted into the vagina as shown. The speculum includes a lower fixed blade 10 having a depending handle portion 12. An upper pivotal blade 14 generally extends parallel to lower blade 10 and has depending ears 16 at the proximate by which it is pivotally mounted on a support 18. Support 30 18 has a yoke 20 at the upper end thereof to which ears 16 are pivoted. The lower portion of support 18 has a

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longitudinal slot 22 through which a thumb screw 24 extends for tightening against handle 12 to adjust the spacing of upper blade 14 from lower blade 10.

At the pivotal connection between ears 16 and yoke 20 a spring (not shown) may be provided which tends to pivot the upper blade 14 in a counterclockwise direction, as viewed in Figure 1, so that it is moved toward fixed blade 10. However, this movement is limited by the position of nut 26 on threaded adjustment rod 28. Conveniently, rod 28 extends through a lever 30 which is fixedly attached to one of the ears 16 of upper pivotal blade 14. Thus, when nut 26 is moved outwardly along rod 28, blade 14 will pivot toward blade 10 and when nut 26 is moved inwardly along rod 28 blade 14 will pivot away from blade 10.

The videoscope V includes a video camera unit 32 mounted on lower blade 10. As previously explained, the video camera unit includes the camera, optics and light delivery system and may also be referred to as an electronic video endoscope. A longitudinal guide member 34 is fixedly attached to stationary blade 10, as best seen in Figure 4. Worm gear 36 is mounted within guide 34, as shown, for rotation about a pin 38. Video camera unit 32 is provided with a rack 40 extending longitudinally therealong and attached thereto. The teeth of the rack engage worm gear 36. A control shaft 42 is attached to pin 38 and has a knob 44 for rotating worm gear 36 and thereby adjusting video camera unit 32 longitudinally along guide 34. This provides a means for focusing the video camera unit on the particular area of the cervix which is being investigated. Advantageously, the video camera unit is sealed against

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moisture leakage into the electronics to allow soaking in a sterilizing or disinfecting solution between usage on different patients. It is usually backfilled with nitrogen during manufacture after air and moisture is removed in a vacuum chamber. A CCD sensor can be used to pickup the image and transmit a signal to the video monitor for processing. The video camera unit case can be made of titanium or other metal which is substantially non-corrosive or it can be made of plastic. The video camera unit can also be sterilized with a gas, such as ethylene oxide.

At the forward end of video camera unit 32 is an optical lens system 46 for receiving an image from the cervix. This lens system may have zoom capabilities to provide 2X to 200X magnification. The image is projected by the camera along cable 48 to a video control unit 50 for projecting an image onto monitor 51 shown in Figure 6A. As shown in Figure 6A, a light source, such as xenon light source, 52 projects light through a monochromator 54. Other light sources, such as halogen, mercury vapor, mercury arc, incandescent or laser can be used. The monochromator has the ability to project light of a single wavelength from the light source 52 and to do so in stepped increments. It should have a high output with a frequency range from 200 nm to 1100 nm. By this means, a physician can look at the video monitor while stepping through each light frequency and look for fluorescing lesions on the cervix or in the vagina. It has been found that different types of lesions will fluoresce in response to different light wavelengths.

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The light exits the monochromator 54 through a slit 56 shown in Figure 6B and enters one end of a bundle of optical fibers 58. Conveniently, one end of optical fiber bundle 58 is mounted within a rectangular collar 60 which mates with the end of monochromator 54 for receiving light from slit 56. The other end of optical fiber bundle 58 has a circular collar 62. Collar 62 and the cable 48 for video control unit 50 connect to a cable or light carrier 64 wherein the individual optical fibers 64 are positioned around the outside of the lens system 46, as best seen in Figure 5. Thus, the light image of selected wavelength can be directed substantially uniformly onto the surface of the cervix or vagina. As the monochromator steps the light from one end of the light spectrum to the other, a wavelength will be encountered in which cancerous lesions or lesions caused by viral infection will fluoresce and therefore will be identifiable on the video monitor. The fluorescence of the tissue may be natural fluorescence, or it may be fluorescence produced by substances which selectively enter cancer cells such as hematoporphyrin derivative (HPD).

When this occurs, these lesions can be destroyed by use of a laser beam. This is accomplished by directing the laser beam along an optical fiber 66 which extends through a channel 68 attached to guide member 34. Optical fiber 66 can be provided with steering cables (not shown) for directing the laser to the lesion cite. A KPT-532 laser, carbon dioxide laser or a YAG laser having been found to be satisfactory. Conveniently, a suction channel 70 can be provided adjacent to laser channel 68 for removing smoke caused by destruction of

the lesions. This channel may be connected to a vacuum hose 72, as shown in Figure 3.

An alternative arrangement is shown in Figure 7 wherein a removable band pass filter 74 is provided
05 between the light source 52 and optical fiber bundle 58 for providing selected wavelengths of light to the cervix. A band pass filter is useful when the patient is treated with a substance which will accumulate at the lesion site and be fluorescent under a known wavelength
10 of light. In such a case the band pass filter can be selected to transmit only the desired wavelength frequency. Suitable substances are hematoporphyrin (HPD) or a derivative thereof, such as dehematoporphyrin either (DHE), corins, pheophorbides and coumerins. Also
15 Rhodamine-123 can be sprayed or painted on the cervix. Finally, the site can be tagged with a fluorescent tagged monoclonal antibody.

In a still further simplified embodiment, shown in Figure 8, the light source 52 is directly connected to
20 optical fiber bundle 58. This embodiment can be used wherein the material at the lesion site on the cervix will have fluorescence over a wide range of light wavelengths for identification of lesions.

A number of add-ons may be provided to the
25 apparatus just described. Among these are a character generator for the patient's name, age, etc., video recorder, video printer and suitable image processors.

A further alternative embodiment is shown in Figures 9 and 10 wherein a videoscope V' is removably attached to blade 10 of speculum S by means of a
30 flexible strap 80 fixedly attached to one side of rack 40 and extending around the camera unit body and being

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attached to the other side of rack 40. This attachment may comprise a threaded stud 82 which receives an aperture 84 in the free end of strap 80. This end of strap 80 is held in place by means of a removable nut
05 86.

With this arrangement, the videoscope V' can be used on the speculum S in the manner previously described. However, the blades of the speculum cover much of the surface of the vagina which prevent thorough
10 inspection thereof. Thus, by removing the videoscope from the speculum the scope can then be reinserted into the vagina, as described more fully below so that the areas which were not visible because of the speculum blades can now be examined.

Conveniently, for use without the speculum, the camera can be inserted into a sterile sheath H, as best seen in Figures 11-14. This sheath H is substantially similar to that shown in my U.S. Patent No. 4,878,485 for "Rigid Video Endoscope With Heat Sterilizable Sheath" which issued on November 7, 1989. The sheath includes a cylindrical housing 88 having a window 90 at the distal end thereof and an accordian-folded sleeve 92 at the proximate end thereof. The housing 88 may be provided with one or more channels, such as channel 94 which can provide gas under pressure by means of a valve 96 and extends longitudinally through housing 88 and below window 90, as shown. Similarly, a second channel 98 can be provided through which a steerable device 100 is provided.
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25

When the videoscope V' is inserted within sheath H, it can be held in fixed position by means of oppositely projecting pins 102 at the proximate end thereof which
30

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engage a bayonet slot 104 in an internal sleeve 106 within housing 88, as best seen in Figures 12 and 14. After insertion, sleeve 92 can be pulled longitudinally down cable 48 by means of pull ring 108. Then the
05 sheath and camera can be inserted into the vagina to examine portions which were previously covered with the speculum. Also, this apparatus can be used for inspection of bodily surfaces or in the colon and other areas where lesions might be suspected. Conveniently, a
10 passageway 110 is provided along the exterior of housing 88 through which channels 94 and 98 can extend, as best seen in Figure 14.

Afterwards, the camera unit can be removed from the sheath, resterilized and reattached to a sterile
15 speculum for examination of the next patient. The sheath can be thrown away or resterilized or disinfected and reattached to a sterile speculum for reuse with another patient.

From the foregoing, the advantages of this
20 invention are readily apparent. A simple yet highly useful cervical videoscope has been provided which can easily be used by the doctor to exam the cervix and vagina for cancerous lesions or other abnormalities. Also, because of the small size of the camera unit there
25 is sufficient space between the camera unit and the blades of the speculum for inserting forceps and other instruments that may need to be used. By using the cervical videoscope in combination with a monochromator the physician can step the wavelength of light from one
30 end of the light spectrum to the other until he observes florescence which identifies abnormal cells. Thereupon, he can destroy the cells by use of a laser beam. When

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he observes that no more florescence is occurring, then he can discontinue the operation of the laser, knowing that the lesion has been completely eradicated. Also, a channel for drawing a suction to remove smoke created by
05 the destruction of the lesion can be provided. Finally, the camera is adjustable along a guide on the fixed blade of the speculum to focus it.

It should also be noted that the device may be detached from the vaginal speculum and used along with
10 the sophisticated light sources to look for similar lesions in the rectal area or on other body surfaces. Conveniently, the camera unit, after removal from the speculum, can be inserted into a sterile sheath in fixed relation therewith. This combined unit can then be
15 inserted into the vagina to examine areas which were previously covered by the blades of the speculum. It also can be used for examining the colon and other areas where lesions are suspected.

This invention has been described in detail with
20 reference to particular embodiments thereof, but it will be understood that various other modifications can be effected within the spirit and scope of this invention.

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CLAIMS

1. A cervical videoscope apparatus including a vaginal speculum having a first fixed blade, a second blade mounted for pivotal movement toward and away from said fixed blade and spring means normally urging said second blade toward said first fixed blade, the improvement comprising:

05 a track mounted longitudinally along one of said blades;

10 a video camera unit removably mounted on said track;

means on said track for removably attaching said video camera unit to said track; and

means for adjustably positioning said video camera unit along said track for focusing.

2. Apparatus, as claimed in Claim 1, wherein said attaching means comprises:

05 a strap, having a first end fixedly attached to a first side of said track, extending around said video camera unit and having a second end with means for releasably attaching it to a second side of said track.

3. Apparatus, as claimed in Claim 2, wherein said releasable attaching means includes:

a pin on said second side of said track;

05 an aperture in said second end of said strap having a diameter just slightly larger than the diameter of said pin so as to be received thereover; and

removable fastening means attached to the end of said pin to hold said second end in place.

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4. A videoscope apparatus for examining various internal body surfaces for lesions having predetermined characteristics, said apparatus comprising:

05 a generally cylindrical elongated video camera unit for insertion in various body cavities and passageways for viewing lesions and having an electronic cable extending from a distal end thereof;

10 a light carrier attached to and generally surrounding said video camera unit and extending from said video camera unit and along said electronic cable as an optical bundle for transmitting light from a source to the field of view of said video camera unit;

15 an outer cylindrical heat sterilizable sheath, having a distal end and a proximate end, for receiving said video camera unit and light carrier and being substantially the same length as said video camera unit;

20 a window sealed to said distal end of said sheath; and

an accordian-folded, heat sterilizable, cylindrical sleeve mounted adjacent said proximate end of said sheath and extendable along said electronic cable and said optical bundle for a substantial distance for maintaining sterility of said video camera unit within an operating room.

5. Apparatus, as claimed in Claim 4, further including:

means for releasably locking said video camera unit within said sheath in a predetermined orientation.

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6. Apparatus, as claimed in Claim 4, wherein said releasable locking means includes:

a bayonet slot at said proximate end of said sheath; and

05 a pin at said proximate end of said video camera unit which is releasably engageable with said bayonet slot.

7. Apparatus, as claimed in Claim 4, further including:

at least one channel connected to said sheath, said channel having a distal end adjacent said window to 05 provide access to a site under investigation.

8. Apparatus, as claimed in Claim 7, wherein:

means supplying an insufflation gas is provided through said one channel to distend the area being examined for greater ease of examination; and

05 valve means connected to a proximate portion of said one channel to control the flow of gas.

9. Apparatus, as claimed in Claim 8, further including:

05 a second channel connected to said sheath, said second channel having a distal end adjacent said window to provide a second access to the site under investigation; and

a steerable device insertable through said second channel for carrying out a procedure on a lesion located at the site.

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10. A method of examining various internal body surfaces for lesions having predetermined characteristics, said method comprising the steps of:

05 mounting a video camera unit and a source of illumination on a blade of a vaginal speculum, wherein the video camera unit has a cable trailing from the distal end thereof and the light source has an optical bundle trailing from the distal end thereof;

10 inserting the speculum into the vagina of the patient;

15 illuminating the cervix and inspecting it for lesions;

removing the speculum from the vagina and removing the video camera unit and illumination source from the speculum;

20 inserting the video camera unit and illumination source into a cylindrical, sterilizable sheath, having a window at a distal end and an accordian-folded cylindrical sleeve adjacent the proximate end;

25 pulling the sleeve over the trailing cable and optical bundle;

inserting the sheath, with the video camera unit and light source in place into one or more body passageways to position the video camera unit for viewing a selected site; and

examining the site for lesions.

11. A method, as claimed in Claim 10, including the further steps of:

removing the sheath from the passageway;

removing the sheath from the video camera unit

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05 and light source;

sterilizing or disinfecting the video camera unit and light source; and

attaching the video camera unit and light source to the blade of a sterile speculum for examining
10 another patient.

12. A method, as claimed in Claim 10, including the further steps of:

removing any lesions found.

13. A method, as claimed in Claim 10, including the further step of:

supplying insufflation gas through a channel in the sheath to distend the area being examined.

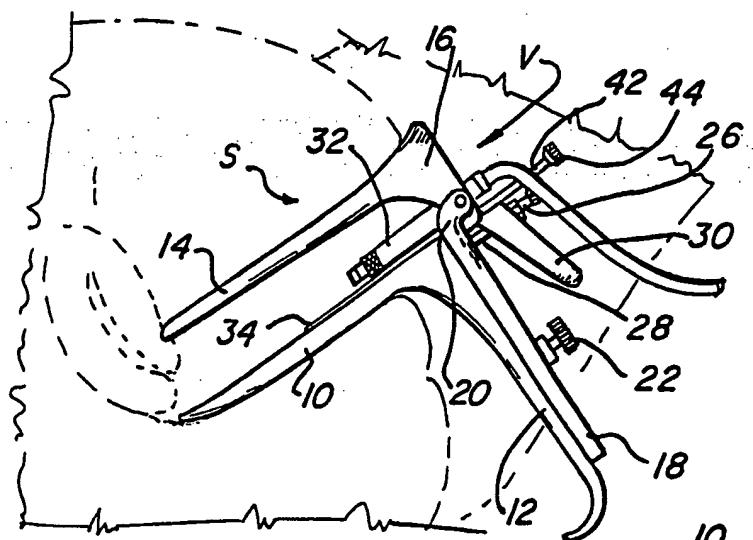
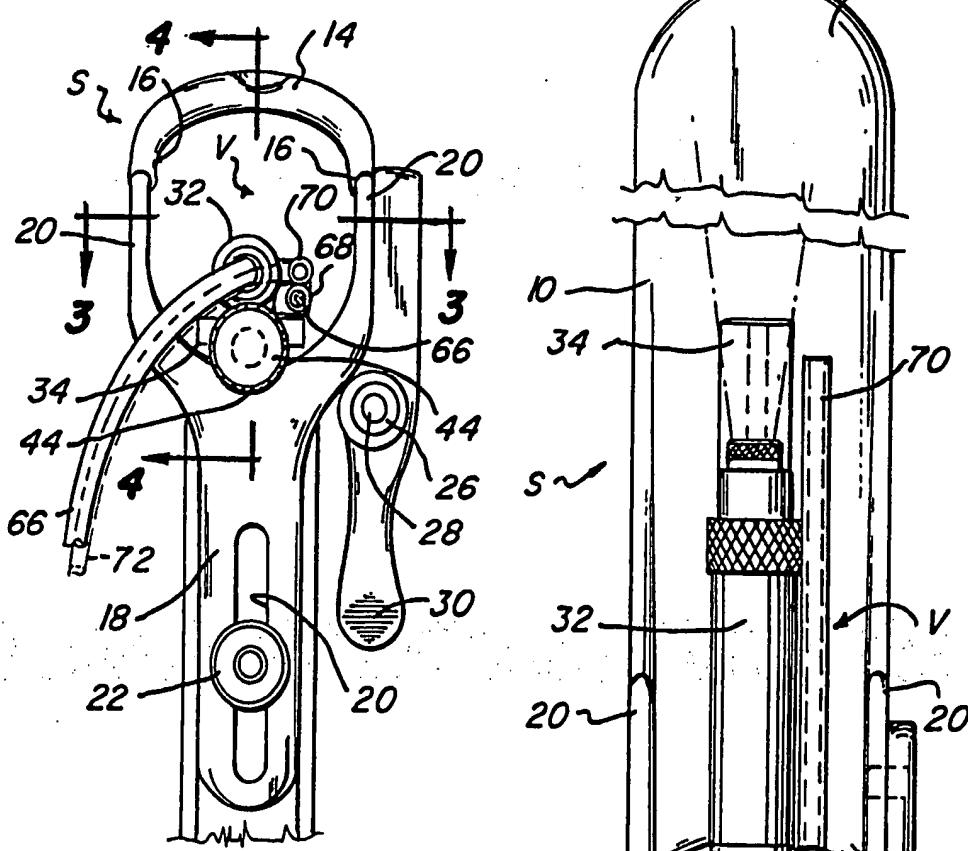
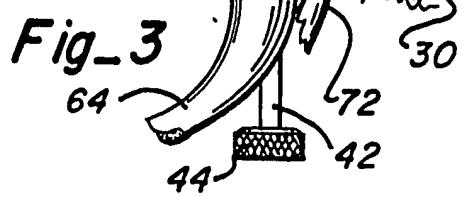
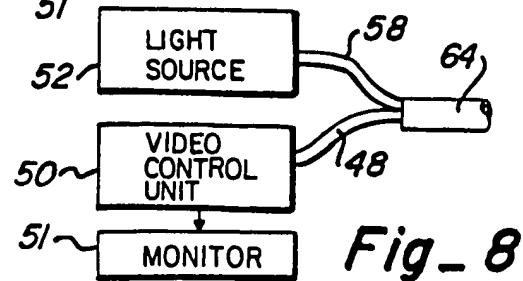
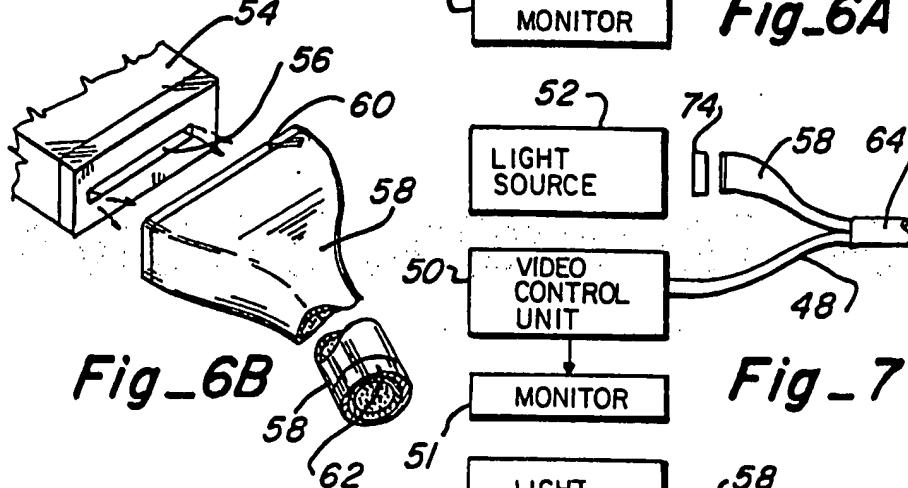
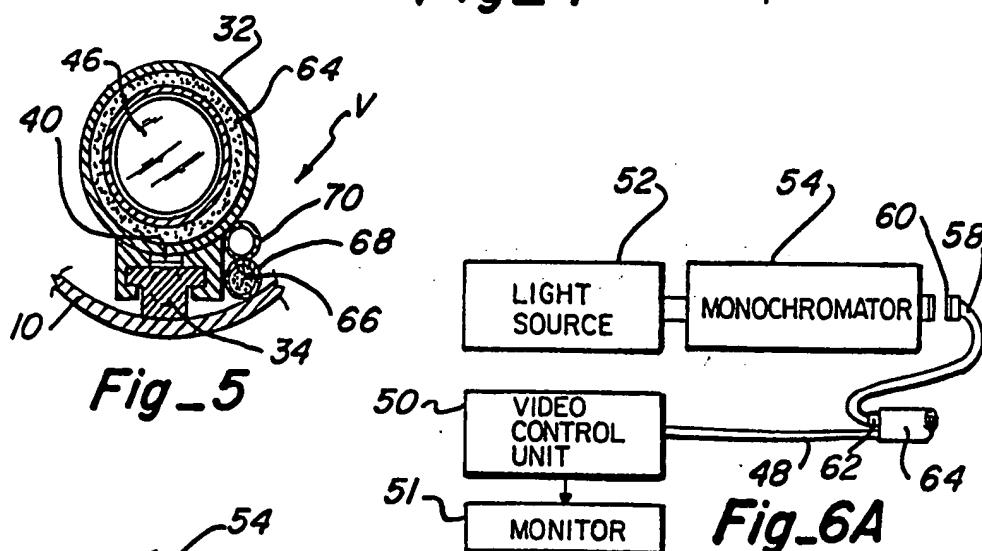
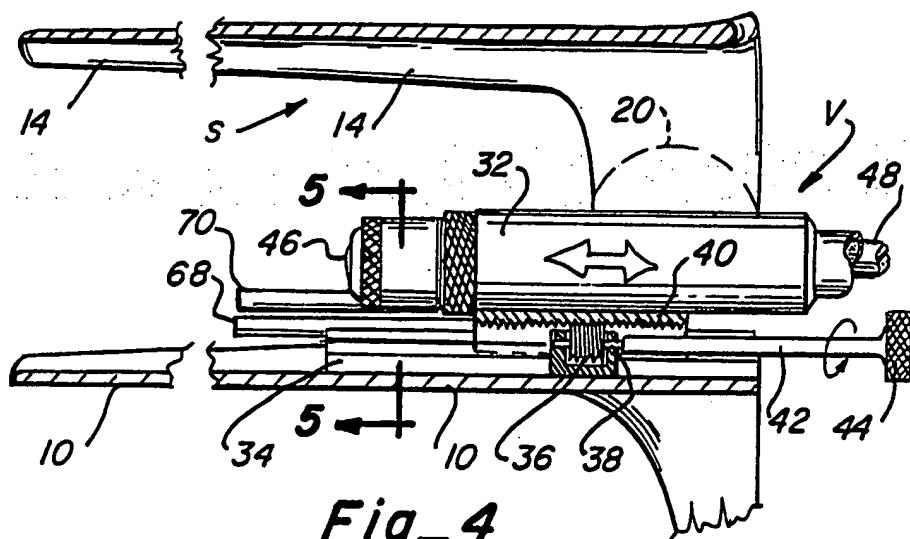


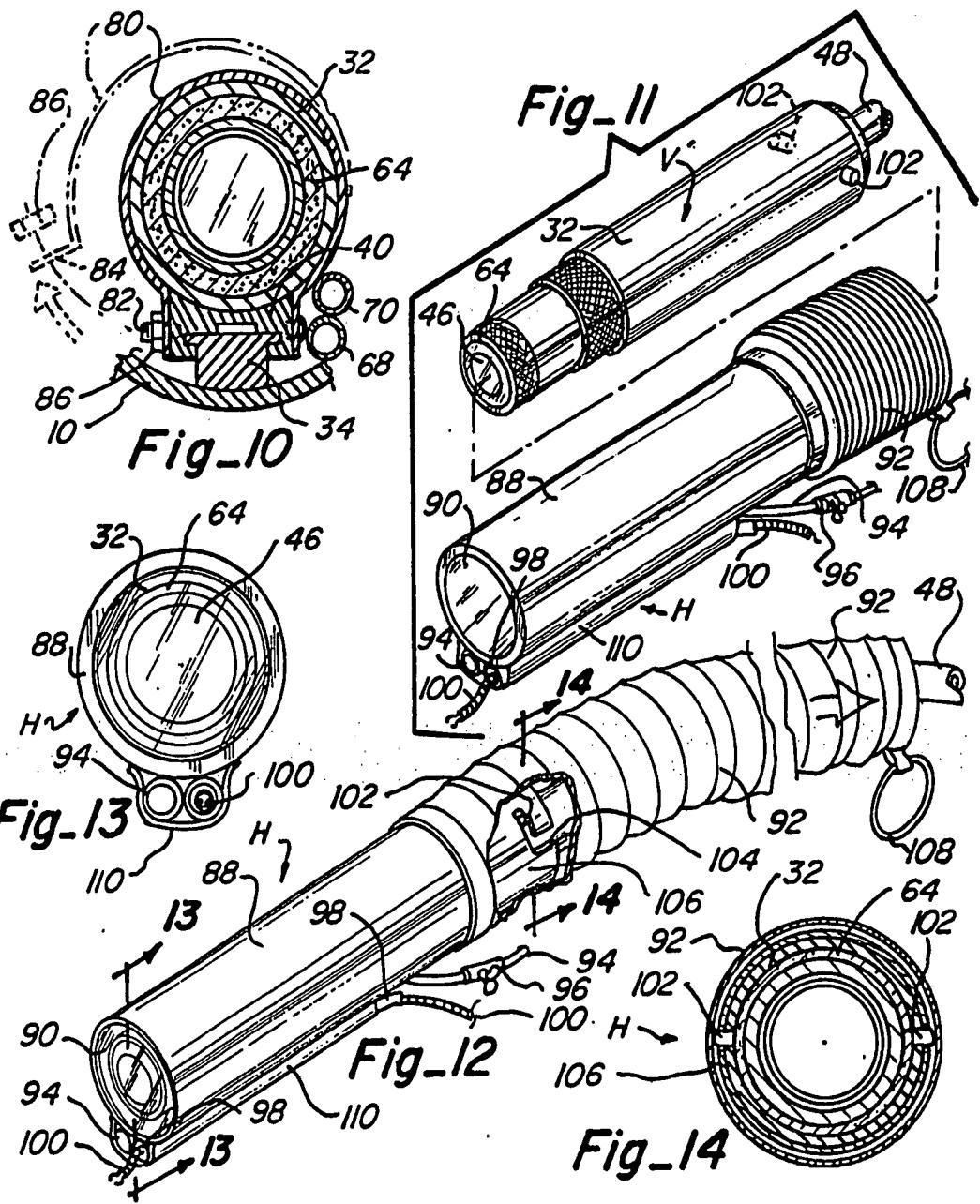
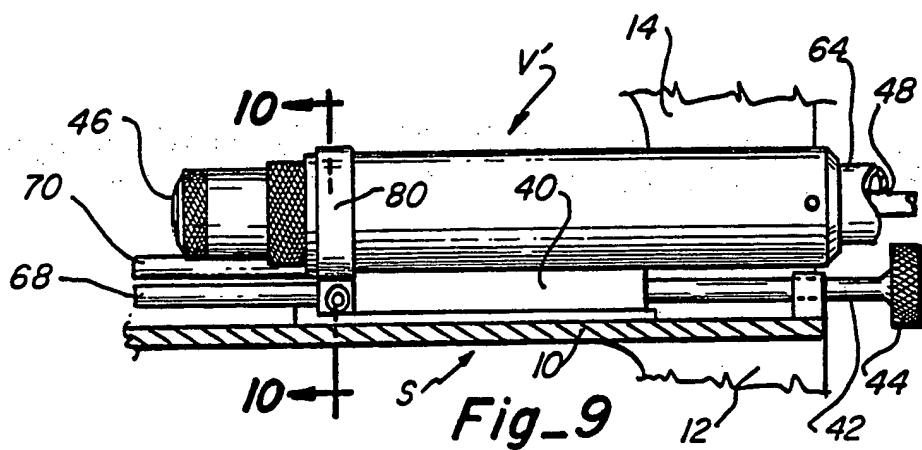
Fig-1



Fig_2







INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 92/03539

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)⁶

According to International Patent Classification (IPC) or to both National Classification and IPC
 Int.Cl. 5 A61B1/32; A61B1/04

II. FIELDS SEARCHED

Minimum Documentation Searched⁷

Classification System	Classification Symbols
Int.Cl. 5	A61B

Documentation Searched other than Minimum Documentation
 to the Extent that such Documents are Included in the Fields Searched⁸

III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹

Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	US,A,4 905 670 (E.L. ADAIR) 6 March 1990 see column 3, line 14 - column 4, line 43 see figures 1-5 cited in the application ---	1 10-12 4,7
Y		
A		
X	US,A,4 878 485 (E.L. ADAIR) 7 November 1989 see column 3, line 64 - column 6, line 29 see figures 6-10 cited in the application ---	4-9,12 10-12 13
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A	US,A,4 915 626 (E.S. LEMMEY) 10 April 1990 see column 2, line 26 - column 3, line 31 ---	1-4,10

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IV. CERTIFICATION

Date of the Actual Completion of the International Search

1

30 JULY 1992

Date of Mailing of this International Search Report

18.08.92

International Searching Authority

EUROPEAN PATENT OFFICE

Signature of Authorized Officer

RIEB K.D.

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO. US 9203539
SA 60283**

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-4905670	06-03-90	EP-A-	0451200	16-10-91
		WO-A-	9007299	12-07-90
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US-A-4915626	10-04-90	None		

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